

entitled "Digifortis Products") "The various Digifortis products provide the medical practitioner with Digitalis preparations of \* \* \* uniform quality. They include Liquid Digifortis," were false and misleading since such statements created the impression that standardization of the article by use of a lethal dose frog method of assay enabled the maintenance of a definite clinical potency for humans, whereas standardization of the article by that method would not enable the maintenance of a definite clinical potency for humans; and (2) the statement on the label and carton of the article, "125% Strength of Tincture Digitalis of International Standard," was false and misleading since it created the impression that the potency of the article was 125 percent of that of tincture of digitalis as described in the United States Pharmacopoeia, which recognizes as a synonym for tincture of digitalis "Tinctura Digitalis P. I. [Protocol Internationale]," whereas the actual strength of the article was more than 200 percent of tincture of digitalis as described in the Pharmacopoeia.

On February 20, 1945, Parke, Davis and Co., claimant, having admitted the facts in the libel, judgment of condemnation was entered and the product was ordered released under bond for remanufacturing and relabeling under the supervision of the Food and Drug Administration.

**1471. Adulteration of Narcosan, Narcosan-A, Elevin, Osmogen, and Sinesin. U. S. v. 6 Boxes of Narcosan, 11 Boxes of Narcosan-A, 2 Boxes of Elevin, 3 Boxes of Osmogen and 3 Boxes of Sinesin. Default decree of condemnation and destruction. (F. D. C. No. 13428. Sample Nos. 53766-F, 53769-F, 53771-F, 53773-F, 53776-F, 53777-F.)**

On August 25, 1944, the United States attorney for the Southern District of California filed a libel against 6 boxes of Narcosan, 11 boxes of Narcosan-A, 2 boxes of Elevin, 3 boxes of Osmogen, and 2 boxes of Sinesin, each box containing 12 ampuls (1-cc. size), and against 1 box containing 30 cc. of Sinesin, at Los Angeles, Calif., alleging that the articles had been shipped by the Lipoidal Laboratories, from New York, N. Y. It was also alleged that shipments of the Narcosan and Narcosan-A were made on or about June 28 and October 15, 1943, respectively, and that the shipment dates of the other articles were unknown.

Examination showed that the articles, each of which bore directions for intramuscular administration, were contaminated with living micro-organisms and therefore unsuitable for intramuscular administration.

The articles were alleged to be adulterated in that their purity and quality fell below that which they purported and were represented to possess.

On September 19, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

**1472. Adulteration of triple distilled water. U. S. v. 270 Ampuls and 1,990 Ampuls of Triple Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 14010. Sample No. 64073-F.)**

On or about October 12, 1944, the United States attorney for the Northern District of Georgia filed a libel against 270 5-cc. ampuls and 1,990 10-cc. ampuls of triple distilled water at Atlanta, Ga., alleging that the article had been shipped on or about August 10, 1944, by the American Medical Specialties Co., Inc., from New York, N. Y.

The article was alleged to be adulterated in that it purported to be and was represented as water for injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since the compendium provides that water for injection is a clear liquid, whereas the article was not a clear liquid but contained suspended material.

On March 16, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1473. Adulteration of triple distilled water. U. S. v. 350 Ampuls of Triple Distilled Water. Default decree of condemnation. Product ordered delivered to the Food and Drug Administration. (F. D. C. No. 13819. Sample No. 78856-F.)**

On September 26, 1944, the United States attorney for the Eastern District of Michigan filed a libel against 350 ampuls, 10-cc. size, of the above-named product at Detroit, Mich., alleging that the article had been shipped on or about July 15, 1944, by the Torigian Laboratories, Inc., Queens Village, N. Y. The article was labeled in part: "Triple Distilled Water for Injection."

Examination showed that the article contained pyrogens and was contaminated with undissolved material.

The article was alleged to be adulterated in that it purported to be and was represented as water for injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it failed to meet the pyrogen test prescribed in the Pharmacopoeia, and it contained undissolved material.

On December 8, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration, for technical use.

**1474. Adulteration of adhesive plaster. U. S. v. 852 Spools and 35,100 Rolls of Adhesive Plaster. Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 14012, 14429. Sample Nos. 52976-F, 92906-F.)**

On or about October 5 and November 14, 1944, the United States attorney for the District of Maryland filed libels against 852 spools and 35,100 rolls of adhesive plaster at Baltimore, Md., alleging that the article had been shipped on or about April 18, 1944, by the Richmond Army Service Forces Depot, from Bellbluff, Va. The article was labeled in part: "Gotham Adhesive Plaster \* \* \* Manufactured by Gotham Aseptic Laboratory Co. Inc. New York, N. Y."

The article was alleged to be adulterated in that it purported to be and was represented as adhesive plaster, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard since the compendium provides that the adhesive strength of adhesive plaster, when determined by the method specified therein, shall be not less than 40 pounds, whereas the adhesive strength of the product in spools was from 3 to 19 pounds and that in rolls was from 3 to 11 pounds.

On November 14, 1944, no claimant having appeared for the spools of the product, judgment of condemnation was entered and that portion was ordered destroyed. On January 17, 1945, B. Pierce and Co., Inc., Baltimore, Md., having appeared as claimant for the remainder of the product and having admitted that the article was adulterated, judgment of condemnation was entered and the article was ordered released under bond to be disposed of in compliance with the law. It was not to be used as surgical adhesive plaster.

**1475. Adulteration of adhesive plaster. U. S. v. 16½ Cartons of Adhesive Plaster. Default decree of condemnation and destruction. (F. D. C. No. 14394. Sample No. 2523-F.)**

On November 9, 1944, the United States attorney for the Eastern District of Oklahoma filed a libel against 16½ cartons, each full carton containing 144 packages, of adhesive plaster at Wewoka, Okla., alleging that the article had been shipped on or about April 28 and July 24, 1944, by the Maryland Salvage Co., from Baltimore, Md. The article was labeled in part: "Gotham Adhesive Plaster \* \* \* Manufactured By Gotham Aseptic Laboratory Co. Inc. New York, N. Y."

The article was alleged to be adulterated in that it purported to be and was represented as adhesive plaster, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard, which provides that the adhesive strength of adhesive plaster, when determined by the method specified therein, shall be not less than 40 pounds, whereas the adhesive strength of the article was from 3 to 19 pounds.

On January 16, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1476. Adulteration of Sanette Treated Strips. U. S. v. 49½ Gross Packages of Sanette Treated Strips. Default decree of condemnation and destruction. (F. D. C. No. 14469. Sample No. 75658-F.)**

On November 11, 1944, the United States attorney for the Western District of Pennsylvania filed a libel against 49½ gross packages of Sanette Treated Strips at Pittsburgh, Pa., alleging that the article had been shipped on or about September 29, 1944, from Yonkers, N. Y., by C. I. Lee and Co., Inc. The article was labeled in part: "Sanette 8 Treated Strips Sanette Mfg. Co. New York, N. Y."

Each package of the article contained a number of individual dressings prepared by affixing an absorbent compress, composed of several layers of absorbent gauze, to a strip of adhesive plaster.

The article was alleged to be adulterated in that it purported to be adhesive absorbent gauze, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.